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Position Statement
on

Latex Allergy

SUMMARY: Natural rubber latex allergy is a serious medical problem for a growing number of patients and a disabling occupational disease among health care workers. Latex allergy develops from exposure to natural rubber latex, a plant cytosol that is used extensively to manufacture medical gloves, other medical devices, and numerous consumer products. Allergic reactions to latex range from skin disease to asthma and anaphylaxis that can result in chronic illness, disability, career loss, hardship, and death. There is no treatment for latex allergy except complete avoidance of latex. Patients and health care providers must be assured safety from iatrogenic sensitization and allergic reactions to latex. Therefore, the American Nurses Association supports immediate interventions to reduce the risk of latex sensitization and ensure safe outcomes for latex-sensitized patients and personnel in all health care settings. Successful interventions will require collaboration between health care providers and administrators, with support from the research community, government agencies, manufacturers, professional organizations, sensitized patients, and patient advocacy groups.

BACKGROUND

Delayed contact dermatitis from chemicals in rubber has been recognized since the 1930s.⁴ But except for rare early reports, clinicians did not appreciate systemic allergic reactions to latex proteins until 1979, when case reports began to appear in Europe. Latex allergy erupted in the United States shortly after the Centers for Disease Control introduced universal precautions in 1987. By late 1992, the Food and Drug Administration (FDA) received 1133 reports of serious allergic reactions and anaphylaxis occurring to patients and health care staff associated with 30 classes of latex medical devices. There were 15 patient deaths associated with latex barium enema catheters.^{5,6} The FDA estimated that the reports represented only 1% of actual occurrences! Today, researchers hypothesize that the latex allergy outbreak is the result of multiple factors including deficiencies in manufacturing processes, increased latex exposure, hand care practices, immunological cross reactivity, and changes in latex agricultural practices.^{1,7,8, 45}

Latex allergy affects between 8%-12 % of workers in all health disciplines. Latex allergy also affects up to 51% of children with spina bifida, and approximately 1% of the general population."

Definitions

Two types of allergies are associated with rubber: a) chemical contact dermatitis, and b) latex protein immediate hypersensitivity, which is termed latex allergy.

Chemical contact dermatitis is a delayed cell-mediated Type IV localized allergy that is caused by chemicals used to manufacture rubber products. The most common contact sensitizers are the accelerators: **thiurams**, mercaptobenzothiazols (**MBTs**), and carbamates.¹

Latex allergy is a Type 1 IgE-mediated hypersensitivity reaction that involves systemic **antibody** formation to proteins in products made from natural rubber latex. Natural rubber latex is harvested commercially from the rubber tree, *Hevea brasiliensis*, and used to manufacture rubber products. Natural rubber latex contains up to 240 potentially allergenic protein fragments, and different persons may be sensitized to different combinations of latex allergens? Synthetic latexes (e.g. synthetic latex paint or synthetic rubber) are not involved in latex **allergy**; therefore, this document refers only to natural rubber latex, henceforth termed latex.

Contact dermatitis, including both irritant and allergic responses, is the most **common** clinical reaction associated with the use of latex gloves. Irritant contact dermatitis is not an allergy.

Physiologic Effects, Diagnosis and Treatment

Latex exposure occurs through contact with the skin or mucous membrane, and by inhalation, ingestion, **parenteral** injection or wound inoculation. Data on the dose and duration of exposure, and the specific proteins required to produce sensitization are incomplete. Risk factors include occupational exposure to latex, multiple surgical procedures or mucosal instrumentation involving latex, and a personal or family history of allergies. Other unrecognized risk factors may **exist**.¹⁶

Latex sensitization causes skin disease, **urticaria**, angioedema, rhinoconjunctivitis, sinusitis, asthma, gastrointestinal symptoms, anaphylaxis and death.*” Symptoms may present **gradually** and progress, although some individuals skip this progression and experience an abrupt onset of anaphylaxis or **asthma**.¹⁹ Highly sensitized individuals can react to minute latex **exposures**.^{7,19} Sensitized persons also may develop immunologic cross-reactivity with fruits and vegetables that may have molecular structures analogous to latex, such as avocado, banana, European chestnut, the drupes (e.g., almond, cherry, peach, nectarine, etc.), kiwi, papaya, tomato, potato and **others**.^{7,19,20}

There is no treatment for latex allergy except complete avoidance of latex, although eventually immunotherapy may become **available**.^{12,21} Early diagnosis and latex avoidance are essential because continued exposure can lead to advanced allergic symptoms that disrupt careers and everyday living, and create serious barriers to health **care**.¹⁹ Latex-sensitized persons should take the following precautions: a) avoid all contact with latex, b) carry auto-injectable **epinephrine**, and consult physicians for alternatives to beta blockers that are prescribed for other conditions, c) wear a medical identification bracelet, and d) negotiate with hospitals and providers in advance for latex-safe health and dental care. In turn, providers must be prepared to identify sensitized patients and deliver all levels of patient care, including emergency treatment, using **nonlatex** medical devices in an environment that is free of latex **contamination**.^{19,22,23}

Medical Glove Allergenicity and Safe Use Practices

Latex medical gloves are the most prominent source of latex allergen exposure by cutaneous

contact, inhalation, wound inoculation and **ingestion**.^{27,48} Allergens levels vary considerably in gloves from different manufacturers, and from lot to lot, with higher levels occurring in powdered gloves and examination gloves than in powder-free gloves and surgical **gloves**.^{24,27} Latex gloves that are inadequately processed during manufacture contain loosely-bound protein that readily rubs off or leaches into sweat, then accumulates on glove wearers' hands and easily transfers by touch to other persons and objects (e.g. medical records, telephones, doorknobs, food, **etc.**).²⁸ Therefore, it is essential that glove users wash their hands between glove changes and after removal, and avoid touching objects or latex-sensitized persons with latex gloves or unwashed **hands**.^{4,28} Glove powder is a strategic factor in allergen exposure. Cornstarch donning powder actively extracts and binds protein from latex, which accumulates on glove wearers' hands, transfers onto objects, and aerosolizes.²⁸ Airborne particles of powder and protein may remain suspended for up to 5 hours, contaminating the air, ventilation system, skin, hair, **clothing**, wounds, and objects which can result in occupational **asthma**.^{29,46} Therefore, health care providers must never use latex gloves in the care of latex-sensitized patients and must not use powdered latex gloves in general.^{4,21,30,46,47} Low allergen, powder-free gloves decrease allergen **exposure**,^{4,28,29,31,32} and also reduce the incidence of allergic reactions and occupational asthma among sensitized **workers**.^{4,21,33,34}

Glove-Associated Hand Dermatitis

Hand dermatitis, which is endemic among glove users, frequently is associated with occupational latex allergy.^{35,36} Skin damage caused by dryness, irritation, contact dermatitis, or other dermatoses not only increases the risk of exposure to pathogens, but also **may enhance** absorption of glove chemicals and **latex protein** allergens.' Hand dermatitis may be a manifestation of either chemical contact dermatitis or latex allergy;' or co-existent contact dermatitis and latex **allergy**.³⁶ Therefore, glove wearers who develop hand dermatitis should seek early medical differential diagnosis that includes patch testing for glove chemical allergy, and latex allergy **testing**.^{36,37} Although glove wearers with dermatitis commonly believe they are allergic to glove powder, sensitization to glove powder has never been shown conclusively." Therefore, symptomatic persons should not delay in seeking differential diagnoses from physicians who are knowledgeable about glove-related allergies.

Glove wearers who use oil-based hand care products or medications to treat skin conditions increase their risk of exposure to allergens and microorganisms. Oil-based ingredients (e.g., jojoba, aloe **vera**, palm oil, coconut oil, lanolin, mineral oil, **petrolatum** products) degrade the molecular structure of latex and some synthetic glove materials within a few minutes, releasing protein and chemicals, and facilitating the passage of **microorganisms**.^{4,38} Alternatively, water or glycerin-based hand care products are compatible with latex. Soaps, detergents, alcohol and various chemicals also degrade latex. Therefore, latex medical gloves are inappropriate for hospital housekeeping because they increase staff exposure to microorganisms and allergens,³⁹ and can contaminate the environment with allergens. Similarly, latex medical gloves are inappropriate for food service workers because they produce unnecessary risk for hand dermatitis and latex allergy, and may contaminate food with latex proteins, resulting in allergic reactions in sensitized persons."

Glove Selection

Once a diagnosis of contact dermatitis or latex allergy is established, employers must provide

gloves **that** are **free** of the causative agent.” Workers who have chemical contact dermatitis require gloves that have been sufficiently processed to remove the sensitizing chemical, and **latex**-sensitized persons must never wear latex gloves.^{4,19,21,42} The “hypoallergenic” label generally means that gloves are low in chemical contact sensitizers, but “**hypoallergenic**”, does **not** refer to latex allergens in gloves.’

RECOMMENDATIONS

Therefore, the American Nurses Association recommends the following actions to protect patients and **personnel** from latex allergy in all health care settings:

1. Based on current research, all health care institutions should eliminate the unnecessary use of latex gloves and implement the use of low-allergen, powder-free latex gloves in all other **settings**.^{3,46,47}
2. Each facility shall convene a multidisciplinary latex allergy task force to develop **patient care** guidelines to:
 - a) ensure that the environment is free of contamination by latex and other substances carried by glove powder;
 - b) identify latex-sensitized patients and those at risk, instruct them about self-care, and deliver latex-safe care in accordance with recommended practice guidelines;
 - c) establish an inventory of **nonlatex** alternatives for latex medical devices;
 - d) develop procedures to identify and resolve problems with medical devices relevant to allergic reactions or glove performance;
 - e) report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone **1-800-FDA-1088**, Fax **1-800-FDA-0178**).
3. **Each** health facility shall develop multidisciplinary latex allergy **occupational health** guidelines that will:
 - a) ensure a workplace that is free of contamination by latex and other substances carried by glove powder;
 - b) educate personnel regarding latex allergy and related issues of hand care, hand dermatoses, glove use, product problem reports, and continued adherence to universal precautions;
 - c) provide task-appropriate, powder-free, low allergen gloves, and enlist manufacturers’ support to resolve glove-related problems;
 - d) facilitate early identification, diagnosis, treatment and tracking of personnel with hand dermatoses or symptoms of latex allergy;
 - e) report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone **1-800-FDA-1088**, Fax **1-800-FDA-0178**);
 - f) accommodate latex-sensitized employees safely in the workplace, assist disabled employees to obtain rehabilitation services, and direct disabled personnel to

compensatory benefits when rehabilitation is not possible.

4. All health personnel shall:

- a) be knowledgeable of latex allergy and its related issues;
- b) implement latex allergy guidelines pertaining to the safety of patients and staff;
- c) seek occupational health services and medical care for early diagnosis and treatment of hand dermatoses and symptoms suggestive of latex allergy and request documentation of glove-associated illness to OSHA;
- d) report allergic events related to latex medical devices to the Food and Drug Administration **MedWatch** Program (phone 1-800-FDA-1088, Fax 1-800-FDA-0178) ;
- e) be knowledgeable about employees' rights to workplace safety, reasonable accommodations for latex-sensitized personnel to remain employed, rehabilitation services, and compensatory benefits for disability when rehabilitation is not possible.

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Related Past Actions: 1995 - Hazardous Workplace Air Quality
 1994 - Risk Versus Responsibility in Providing Nursing Care
 1993 - Health and Safety in the Workplace
 1984 - Employees Right to Know Hazards in the Workplace
 1982 - Health Hazards in the Workplace

FOOTNOTES

1. Truscott, W. (1995). The industry perspective on latex. *Immunology and Allergy Clinics of North America*, 15(1), 89-121.
2. Alenius, H., Kurup, V., Kelly, K., Palosuo, T., Turjanmaa, K. & Fink, J. (1994). Latex allergy: Frequent occurrence of IgE antibodies to a cluster of 11 latex proteins in patients with spina bifida and histories of anaphylaxis, *Journal of Laboratory and Clinical Medicine*, 123, 712-720.
3. Kelly, K.J., Sussman, G., & Fink, J.N. (1996). Stop the Sensitization. *Journal of Allergy and Clinical Immunology*, 98, 857-859.
4. Truscott, W. & Roley, L. (1995). Glove-associated reactions: Addressing an increasing concern. *Dermatology Nursing*, 7(5), 283-292.
5. Granady, L.C. & Slater, J.E. (1995). The history and diagnosis of latex allergy. *Immunology and Allergy Clinics of North America*, 15(1), 21-29.
6. Levy, D.A. (1993). Report on the International Latex Conference: Sensitivity to Latex in Medical Devices, Baltimore, MD, USA 5-7 November, 1992. *Allergy*, 48(4, Suppl.) 1-9.
7. Charous, B.L. (1994). The puzzle of latex allergy: Some answers, still more questions. *Annals of Allergy*, 73(4), 277-281.
8. Hamann, C.P. (1993). Natural rubber latex protein sensitivity in review. *American Journal of*

Contact Dermatitis, 4(1), 4-21.

9. Food and Drug Administration, Center for Devices and Radiological Health. (1993). *Regulatory requirements for medical gloves: A workshop manual* (HHS Publication No. FDA 934257). Rockville, MD: Center for Devices and Radiological Health.
10. Food and Drug Administration, Center for Devices and Radiological Health. (1992). *Program and proceedings: International Latex Conference: Sensitivity to Latex in Medical Devices*. Rockville, MD: Center for Devices and Radiological Health.
11. Food and Drug Administration and Health Industry Manufacturers Association. (undated). *Gloves: Information about medical gloves*. Rockville, MD: Food and Drug Administration, Center for Devices and Radiological Health.
12. American College of Allergy, Asthma and Immunology. (1995). Latex allergy - an emerging health care problem. *Annals of Allergy, Asthma & Immunology*, 75(1), 19-21.
13. Food and Drug Administration, Center for Devices and Radiological Health. (1995, March 9). *Interim guidance for protein content labeling claim for latex medical gloves (letter)*. Rockville, MD: Center for Devices and Radiological Health.
14. Food and Drug Administration, Center for Devices and Radiological Health. (1995). *To medical glove manufacturers* (letter). Rockville, MD: Food and Drug Administration, Center for Devices and Radiological Health.
15. Food and Drug Administration. (1995, March 24). *Latex allergy test cleared for marketing* (FDA Talk Paper). Rockville, MD: Food and Drug Administration Press Office.
16. Kelly, K. J., Kurup, V.P., Reijula, K.E. & Fink, J.N. (1994). The diagnosis of natural rubber latex allergy. *Journal of Allergy and Clinical Immunology*, 93(5), 813-816.
17. Ownby, D.R., Ownby, H.E., McCullough, J.A., & Shafer, A.W. (1994). The prevalence of anti-latex IgE antibodies in 1000 volunteer blood donors. *Journal of Allergy and Clinical Immunology*, 93(1, Pt. 2), 282. (Abstract No. 717).
18. Thompson, R.L. (1995, November 16) *Educational challenges of latex allergy*. Paper presented at Latex Allergy: A One Day Seminar, Chicago.
19. Kelly, K.J. (1995). Management of the latex-allergic patient. *Immunology and Allergy Clinics of North America*, 15(1), 139-157.
20. Beezhold, D.H., Sussman, G.L., Liss, G.M. & Chang, N.S. (1996). Latex allergy can induce reactions to specific foods. *Clinical and Experimental Allergy*, 26(5), 416-422.
21. Slater, J.E. (1994). Latex allergy. *Journal of Allergy and Clinical Immunology*, 94 (2, Pt. 1), 139-50.
22. American Academy of Allergy & Immunology. (1993). Task Force on Allergic Reactions to Latex: Committee Report. *Journal of Allergy and Clinical Immunology*, 92(1, Pt. 1), 16-18.
23. American College of Allergy & Immunology, Task Force on Latex Hypersensitivity. (1992). Interim recommendations to health professionals & organizations regarding latex allergy precautions. Palatine, IL: American College of Allergy & Immunology.
24. Jones, R.T., Scheppmann, D.L., Heihnan, D.K. & Yunginger, J. W. (1994). Prospective study of extractable latex allergen contents of disposable medical gloves. *Annals of Allergy*, 73(4), 321-325.
25. Wrangsjö, K. & Lundberg, M. (1996). Prevention of latex allergy. *Allergy*, 51(1), 65-67.
26. Alenius, H., Makinen-Kiljunen, S., Turjanmaa, K., Palosuo, T. & Reunala, T. (1994). Allergen and protein content of latex gloves. *Annals of Allergy*, 73(4), 315-320.
27. Yunginger, J.W. (1995). Variances in antigenicity of latex products. *Immunology and Allergy Clinics of North America*, 15(1), 61-70.
28. Beezhold, D.H., Kostyal, D.A. & Wiseman, J. (1994). The transfer of protein allergens from latex gloves: A study of influencing factors. *AORN Journal*, 59(3), pp. 605, 607-608, 610,

612-613.

29. Swanson, M.C., Bubak, M.E., Hunt, L.W., Yunginger, J.W., Warner, M.A. & Reed, C.E. (1994). Quantification of occupational latex aeroallergens in a medical center. *Journal of Allergy and Clinical Immunology*, **94**(3, Pt. 1), 445-451.
30. Kelly, K. (1993). Management of the latex-allergic patient. *Immunology and Allergy Clinics of North America*, **15**(1), 139-157.
31. Siu, S.R., Smith, G.J., Sussman, G.L., Swanson, M.C., Yunginger, J., Cividino, M.P., Brown, S.A. & Beezhold, D. (1996). Reduction in airborne latex protein exposure by use of low protein, powder-free gloves. *Journal of Allergy and Clinical Immunology*, **97**(1, Pt. 3), 325. (Abstract No. 569).
32. Abbosh, J., Ownby, D. & McCullough, J. (1996). Quantitation of airborne latex allergens produced by bursting and snapping latex gloves. *Journal of Allergy and Clinical Immunology*, **97**(1, Pt. 3), 429. (Abstract No. 985).
33. Tarlo, S.M., Sussman, G., Contala, A. & Swanson, M.C. (1994). Control of airborne latex by use of powder-free latex gloves. *Journal of Allergy and Clinical Immunology*, **93**(6), 985-989.
34. Sussman, G.L., Pugh, B. & Beezhold, D.H. (1996). Latex allergen levels in disposable medical gloves. *Journal of Allergy and Clinical Immunology*, **97**(1, Pt. 3), 326. (Abstract No. 573).
35. Charous, B.L., Hamilton, R.G. & Yunginger, J.W. (1994). Occupational latex exposure: Characteristics of contact and systemic reactions in 47 workers, *Journal of Allergy and Clinical Immunology*, **94** (1), 12-18.
36. Taylor, J.S., & Praditsuwan, P. (1996). Latex allergy: Review of 44 cases including outcome and frequent association with allergic hand eczema. *Archives of Dermatology*, **132**(3), 265-271.
37. Turjanmaa K. (1994). Contact urticaria from latex gloves. In G.A. Mellstrom, J.E. Wahlberg, & H.I. Maibach (Eds.), *Protective gloves for occupational use* (pp. 241-254). Boca Raton, FL: CRC Press.
38. Truscott, W. (1995). They're not just gloves: A guideline on proper use. *Chicago Dental Society Review*, **88**(2), 22-29.
39. Sussman, G.L., Lem, D., Liss, G. & Beezhold, D. (1995). Latex allergy in housekeeping personnel. *Annals of Allergy, Asthma & Immunology*, **74**(5), 415-418.
40. Schwartz, H.J. (1995). Latex: A potential hidden "food" allergen in fast food restaurants. *Journal of Allergy and Clinical Immunology*, **95**(1, Pt. 1), 139-140.
41. Occupational Safety and Health Administration. (1991, December 6). 29 CFR part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Final Rule. *Federal Register*, **56**(235), 64175-64182.
42. Gehring, L.L., Fink, J.N. & Kelly, K.J. (1996). Evaluation of low allergenic latex gloves in latex sensitive patients. *Journal of Allergy and Clinical Immunology*, **97**(1 Pt. 3), 186. (Abstract No. 13).
43. Korniewicz, D. (1996). Barrier protection of latex. *Immunology and Allergy Clinics of North America*, **15**(1), 123-137.
44. Turjanmaa, K., Alenius, H., Makinen-Kiljunen, S., Reunala, T., & Palosuo, T. (1996). Natural rubber latex allergy. *Allergy* **51**, 593-602.
45. Slater, J.E. (1992). Allergic reactions to natural rubber. *Annals of Allergy*, **68**(3), 203-209.
46. American Academy of Allergy, Asthma, and Immunology (AAAAI) and American College of Allergy, Asthma, and Immunology (ACAAI) *Joint Statement Concerning the Use of Powdered and Non-Powdered Natural Rubber Latex Gloves*. Arlington Heights, IL: ACAAI, July 21,

1997.

47. Department of Health and Human Services (DHHS) National Institute for Occupational Safety and Health (NIOSH). *NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace* [DHHS (NIOSH) Publication No. 97-135], 1997.
48. Yunginger, J., Jones, R., Fransway, A. et al. (1994). Extractable latex allergens and proteins in disposable medical gloves and other rubber products. *Journal of Allergy and Clinical Immunology*, 93:83-42.

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